Proposal for Pharmaceutical Excipients in Livestock Treatments and Supplements

Summary of Use:

Excipients are substances other than the active ingredient that are used in the manufacturing process or are found in the finished product. The primary functions of excipients are as binders, disintegrants, fillers (diluents), lubricants*, flow enhances (glidants), compression aids, colors, sweeteners, preservatives, suspending/dispersing agents, film formers/coatings, flavors, anti-microbials and printing inks. Excipients may be used to transport the active drug ingredient to the target site, slow the release of the drug to prevent tissue damage, enhance absorption, disintegrate the drug into small sized particles to allow for movement across membrane, stabilize the drug, or enhance the color and flavor. Excipients are typically the largest percentage of any pharmaceutical product.

Rational:

Excipients are materials such as carriers, inerts and antimicrobials and are not intended to have any effect on the animal being treated.

Recommendation:

The NOSB recommends the addition of a new 205.603 (h) to read as follows: Excipients used in the manufacturing or found in the finished product of drugs used in livestock treatments are allowed unless specifically prohibited.

~~Recommendation:~~

The NOSB recommends that excipients be defined as follows:
Excipeints are substances other than the active ingredient(s) that are used in the manufacturing process or found in the finished livestock pharmaceutical product. The primary function of excipients are as binders, disintegrants, fillers, lubricants, flow enhances, compression aids, colors, sweeteners, preservatives, suspending/dispersing agents, film formers/coatings, flavors, anti-microbials, and printing inks. Excipients may be used to transport the active drug ingredient to the target site, slow the release of the drug, enhance absorption, flavor or color, or disintegrate or stabilize the drug.

*A lubricant is added to prevent a compacted powder from sticking to the equipment when a tablet or capsule is being made. "It also aids the ejection of the tablet from the dies, and in some cases may help improve powder flow."
(http://www.pformulate.com/lubricants.htm)

Excipients Examples (human)

Binders
* Carbopol
* Povidone
* Xanthan Gum

Coatings
* Cellulose Acetate Phthalate
* Ethylcellulose
* Gellan Gum
* Maltodextrin
* Methacrylates
* Methylcellulose
* Microcrystalline Cellulose & carrageenan
* Shellac

Compression/Encapsulation Aids
* Calcium Carbonate
* Dextrose
* Fructose DC
* Honey DC
* Lactose, anhydrate
* Lactose, monohydrate
* Lactose and Aspartame
* Lactose and Cellulose
* Lactose & Microcrystalline Cellulose
* Maltodextrin
* Maltose DC
* Mannitol
* Microcrystalline Cellulose (MC)
* MC and Guar Gum or Lactose
* Molasses DC
* Sorbitol, crystalline
* Starch DC
* Sucrose

Disintegrants
* Croscarmellose Sodium
* Crospovidone
* Gellan Gum
* L-HPC
* Sodium Starch Glycolate
* Starch DC

Creams and Lotions
* Maltodextrin
* Carrageenans

Lubricants
* Magnesium stearate
* Stearic Acid
* Sodium Stearyl Fumarate

Plasticizers
* Dibutyl Sebacate
* Plasticizers for Coatings
* Polyvinylacetate Phthalate

Powder Lubricants
* Glyceryl Behenate

Soft Gelatin Capsules
* Sorbitol Special Solution

Spheres For Coating
* Sugar Spheres

Spheronization Agents
* Glyceryl Behenate
* Microcrystalline Cellulose

Suspending/Gelling Agents
* Carrageenan
* Gellan Gum
* Mannitol DC
* Microcrystalline Cellulose
* Povidone
* Sodium Starch Glycolate
* Xanthan Gum

Sweeteners
* Aspartame
* Aspartame and Lactose
* Dextrose
* Fructose DC
* Honey DC
* Maltodextrin
* Maltose DC
* Mannitol DC
* Molasses DC
* Sorbitol, crystalline
* Sorbitol, Special Solution
* Sucrose DC

Wet Granulation Agents
* Calcium Carbonate
* Lactose, anhydrous
* Lactose, monohydrate
* Maltodextrin
* Mannitol DC
* Microcrystalline Cellulose
* Povidone
* Starch D